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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/621,086

07/15/2003

Yasuo Hirata

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OSTROLENK FABER GERB & SOFFEN  
1180 AVENUE OF THE AMERICAS  
NEW YORK, NY 100368403

EXAMINER

SMITH, PHILIP ROBERT

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

01/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/621,086	<b>Applicant(s)</b> HIRATA, YASUO	
	<b>Examiner</b> Philip R. Smith	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

**Claim Rejections - 35 USC § 102**

- [01] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [02] The rejection of claim 3 as being anticipated by Flaherty (6,726,677) set forth in the Office action of 3/19/2007 is withdrawn in view of the amendments of 6/6/2007.
- [03] Claims 1-2,8,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Flaherty (6,726,677).
- [04] With regard to claim 1: Flaherty discloses an endoscope system comprising:
- [04a] an endoscope having an elongated insertion unit ("probe 84," 8/45) comprising adjoining bending and distal sections thereof;
  - [04b] a guide member for guiding the insertion unit, the insertion unit guide member inherently having proximal and distal guide member ends and including a plurality of tubular members (comprising "catheter 80" and "sheath 86," 8/41-50) having varying outer diameters, each tubular member of the plurality of tubular members inherently having proximal and distal ends and a guide channel of a predetermined inner diameter permitting passage of tubular members having smaller outer diameter and the insertion unit (see Figure 3);
  - [04c] Each of the tubular member inherently has a predetermined degree of flexibility and a predetermined length. The "catheter 80" has a direction changing unit ("distal tip 104" comprising "curved deflecting portion 108," 9/9) operative to change a direction in which the insertion unit is advanced through the guide channel, wherein the insertion unit guide member is adapted to be passed through or placed in a pipe.

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[05] With regard to claim 2: Flaherty further discloses that:

[05a] the direction changing unit ("104," as noted above) is a distal cover member attachable to the distal end of the tubular member;

[05b] the distal cover member has a passing direction changing opening ("side opening 110," 9/10) formed in a lateral side of the distal cover member; and

[05c] the passing direction opening changes the passing direction, in which the insertion unit is passed, from an axial direction of the tubular member to a lateral direction thereof.

[06] With regard to claim 8: Flaherty further discloses that when the insertion unit guide member is being formed, the plurality of tubular members being joined are arranged so that:

[06a] the inner and outer diameters of a tubular member located on the distal guide member end will be smaller than the inner and outer diameters of a tubular member located on the proximal guide member end (see Figure 3);

[06b] a length of the tubular member located on the distal guide member end [is] greater than that of a tubular member located on the proximal guide member end (see Figure 3); and

[06c] the degrees of flexibility of the tubular members are determined so that the tubular member located on the distal guide member end are softer than the tubular member located on the proximal guide member end (see Figure 3).

[07] With regard to claim 10: Flaherty further discloses:

[07a] a balloon ("balloon 76," 14/33) that changes from a contracted state to a dilated state or vice versa is located at the middle of the tubular member;

[07b] and when dilated, the balloon comes into close contact with the wall of the pipe, and the tubular member is locked at a predetermined position in the pipe.

**Claim Rejections - 35 USC § 103**

- [08] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [09] Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (6,726,677) in view of Matsuno (6,605,033).
- [10] Flaherty discloses the entirety of claim 2, as noted above, including a distal cover member. Flaherty does not disclose a leading direction adjusting unit.
- [11] Matsuno discloses a leading direction adjusting unit for adjusting the leading direction in which the insertion unit is led out of the passing direction changing opening (see Figure 3) comprising:
- [11a] a raiser ("direction setting table 5," 4/36-42) located distally to the passing direction changing opening of the distal cover member; and
- [11b] an operation wire ("22") having a wire distal end thereof fixed to the raiser and a wire proximal end extended towards the proximal guide member end.
- [12] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a leading direction adjusting means in the invention of Flaherty in order to vary the direction of the "probe 28."

**Additional Claim Rejections - 35 USC § 103**

- [13] Claims 6,7,9,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (6,726,677) in view of Matsuno (6,605,033) and in further view of Krupa (2003/0216616).
- [14] As noted above, Flaherty or Flaherty in view of Matsuno disclose the entireties of claims 1,3,5. Neither Flaherty nor Matsuno disclose a braid that sheaths the periphery of the tubular member.

- [15] Krupa discloses that bending endoscope typically have braids around them. Braids are flexible materials which are still strong. Krupa discloses in [0037] that

[e]xamples of materials from which layer 404 can be formed include braid or mesh manufactured from, for example, metals, alloys, low-stretch polymers (e.g. nylon, Kevlar), fiberglass, and composites of these materials. Typically, the braid or mesh wire or thread has a round cross section, but other shaped cross-section can be used (e.g., flat, oval).

- [16] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that Flaherty's invention comprise a braid for sheathing a periphery of the tube, as this is well known in the art to be a strong, flexible, and lightweight material.
- [17] Given the plurality of tubes, one of which is inherently capable of facilitating a tool, an operating wire would inherently lie between the braid around the periphery and at least one tube.
- [18] With regard to claim 11: Flaherty discloses a plurality of juxtaposed tubes (e.g. "106" and "116" in Figure 4B).

#### **Additional Claim Rejections - 35 USC § 103**

- [19] Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (6,726,677) in view of Hasegawa (2002/0032365).
- [20] Flaherty does not disclose a drum.
- [21] Hasegawa discloses a drum about which the insertion unit is wound and which has a controller, which controls the bending section, incorporated in a center, and a support for supporting the drum so that the drum can freely rotate (see Figure 17a).
- [22] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to incorporate the drum of Hasegawa into the endoscope of Flaherty. A skilled artisan would be motivated to do so in order to conserve space.

**Allowable Subject Matter**

- [23] Claims 13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Response to Arguments**

- [24] Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive.
- [25] Applicant contends that "[t]here is no discussion in Flaherty of forming a guide member inside the vein before inserting the insertion unit". It is maintained that Flaherty discloses a guide member as defined by claim 1, without regard to its operational usage inside veins.

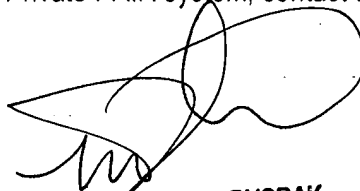
**Conclusion**

- [26] **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- [27] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- [28] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.

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[29] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.

[30] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LINDA C. M. DVORAK  
SUPERVISORY PATENT EXAMINER  
GROUP 3739